DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 0 1 — 1 5

2. STATE: MICHIGAN

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
December 1, 2001

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
Sect. 1927 of S.S.A. (42 USC 1396r-8)
42 CFR 440 and 42 CFR 447

7. FEDERAL BUDGET IMPACT:
a. FFY 2002 $ (22 million)
b. FFY 2003 $ -0-

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Supplement to Attachment 3.1-A page 24 and 24.1
Attachment 4.19-B page 1

Per Nancy Bishop 1/24/02 RAH

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Supplement to Attachment 3.1-A page 24
Attachment 4.19-B page 1

10. SUBJECT OF AMENDMENT:
Pharmacy coverage and reimbursement

11. GOVERNOR'S REVIEW *(Check One)*:

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME: James K. Haveman, Jr.

14. TITLE: Director

15. DATE SUBMITTED: 10-5-01

16. RETURN TO:
Michigan Department of Community Health
Office of Federal Liaison
6th Floor Lewis Cass Building
320 South Walnut Street
Lansing, Michigan 48913
ATTENTION: Nancy Bishop

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 10-10-01

18. DATE APPROVED: 1/24/02

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 12-1-01

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME: Cheryl A. Harris

22. TITLE: Associate Regional Administrator
Division of Medicaid and Children's Health

23. REMARKS:

RECEIVED
OCT 10 2001
DMCH - MI/MN/WI

FORM HCFA-179 (07-92)

Instructions on Back

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: MICHIGAN

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE
AND
SERVICES PROVIDED TO THE CATEGORICALLY AND MEDICALLY NEEDY

12. Drug Products, Dentures, Prosthetic and Orthotic Devices, Eyeglasses

a. Drug Products

1. Drug products are covered when prescribed or ordered by a physician, dentist or other licensed practitioner within the scope of his/her practice and when obtained from a licensed pharmacy.
2. Coverage of selected legend and over the counter products from manufacturers that have not entered into or have in effect a rebate agreement as required are limited to those products essential to the health of the beneficiary and that have a 1-A rating by the Food and Drug Administration. Coverage requires prior authorizaton.
3. Prior authorization may be applied to any drug product, in compliance with federal law.
   (A) A request for prior authorization is processed within 24 hours of receipt.
   (B) A 72-hour supply of medically necessary covered drug products is provided in an emergency situation.
4. Drug products may be restricted from coverage when use is not for a medically accepted indication or when the drug is excluded from Michigan's drug product list, in compliance with federal law.
5. Other drug product restrictions include: i) dosage and quantity limits, ii) refill limits, and iii) other parameters necessary to ensure appropriate utilization or to prevent fraud and abuse.
6. A drug use review program, including prospective and retrospective drug utilization review, has been implemented in compliance with federal law.
7. Claims management is electronic, in compliance with federal law.
8. The state is in compliance with Section 1927 of the Social Security Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for the supplemental rebate program for the Medicaid population:

   (A) A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid population, submitted to CMS on January 15, 2002 and entitled "State of Michigan Supplemental Drug Rebate Agreement" has been approved by CMS.
   (B) Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
   (C) All drugs covered by the program, irrespective of a prior authorization requirement, will comply with provisions of the national drug rebate agreement.

b. Dentures

Dentures are a covered benefit for recipients of all ages if determined necessary by a licensed dentist (Item 10 of the attachments) to correct masticatory deficiencies likely to impair general health. Prior authorization is required. If the client has an existing denture, replacement is permissible only if the existing denture cannot be relined or rebased, whether or not the existing denture was obtained through the Michigan Medical Assistance Program.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: MICHIGAN

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE
AND
SERVICES PROVIDED TO THE CATEGORICALLY AND MEDICALLY NEEDY

Reimbursement for complete or partial dentures includes the costs of any necessary adjustments within six months of insertion. Dentures which are lost, stolen, or broken beyond repair may be replaced only in extraordinary circumstances, and only once every five years.

c. Prosthetic and Orthotic Devices

Such devices are provided under the following conditions only:

1) when provided to a hospital inpatient, upon a physician's order indicating that the device is essential to the client's medical treatment plan; or,

2) when prior authorized as medically necessary and provided on an outpatient basis or for a recipient in a long term care facility.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: MICHIGAN

POLICY AND MEHODS FOR ESTABLISHING PAYMENT RATES (OTHER THAN INPATIENT HOSPITAL AND LONG-TERM CARE FACILITIES)

1. **Individual Practitioner Services**

Payments rates are established by the Michigan Department of Social Services as a fee screen for each procedure. The fee schedule is designed to enlist the participation of an adequate number of providers. The Medicare prevailing fees, the Michigan Relative Value Study and other relative value information, other state Medicaid fee screens, and providers' charges are utilized as guidelines or reference in determining the maximum fee screens for individual procedures.

Providers are reimbursed the lesser of the Medicaid fee screen or the provider's usual and customary charge minus any third party payment. A provider's usual and customary charge should be the fee he most frequently charges his patients with regard to special considerations or financial status.

Annually, the State Legislature appropriates a maximum dollar amount for practitioner services and aggregate payments must not exceed that amount. The State Legislature may also unilaterally increase or decrease fee screens by a specified percentage amount for each fiscal year or part thereof.

The State collaborates with the Michigan Department of Public Health (MDPH) on a Vaccine Replacement Program (VRP). Vaccines are provided free to enrolled Medicaid providers on a replacement basis to immunize Medicaid eligibles. Providers are reimbursed an enhanced administration fee to encourage their participation. The department reimburses the MDPH the government contract price for each dose of vaccine administered, in addition to a per dose handling fee and spoilage allowance. Providers may also request the manufacturer's cost of vaccine if they elect not to participate in the VRP. The department establishes the reimbursement rate for purchased vaccine by allowing the lowest most commonly available cost to purchase the product in multiple dose units plus a nominal administration fee.

2. **Drug Product Reimbursement**

a) Reimbursement for drug products is the lower of an Average Wholesale Price (AWP) minus discounts, a Maximum Allowable Cost (MAC), or the provider's charge. The discount from AWP for chain pharmacies and pharmacies with no retail customers serving long term beneficiaries is 15.1% and the discount from AWP for independent pharmacies, including chains of fewer than five stores, is 13.5%.

b) The State has established dispensing fees. Program reimbursement is the lesser of the standard dispensing fee ($3.77) or the pharmacy's usual and customary fee. The dispensing fee for standard compounds is $6.00 and $10.00 for compounding capsules and suppositories. Long term care pharmacies are paid 3 cents per capsule or tablet for repackaging.

c) MAC Limits set by the State in aggregate are equal to or less than Federal Upper Limits, in compliance with federal law.

d) Prior authorization is required for exception to MAC Limits.

State of Michigan Supplemental Drug-Rebate Agreement

I - PARTIES/PERIOD

This Agreement is made and entered into this _____day of _____ 2001, by and between the State of Michigan (State), represented by the Department of Community Health (Department), and _____(Manufacturer), Labeler Code _____. The parties, in consideration of the covenants, conditions, agreements, and stipulations expressed in this Agreement, do agree as follows:

II - PURPOSE

2.1 It is the intent of this Agreement that the Department will receive a Supplemental Rebate for the Medicaid population, in addition to rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8), for the Manufacturer's Covered Product(s) quarterly utilization in the Michigan Medicaid Program. The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act (42 USC 1396r-8).

III – DEFINITIONS

3.1 'Average Manufacturer Price' (AMP) means Manufacturer's price for the Covered Product(s). AMP will be calculated as specified in Manufacturer's CMS Agreement.

3.2 'Best Price' means, with respect to a Single Source Drug or Innovator Multiple Source Drug of a Manufacturer, the lowest price available from the Manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States, excluding: (a) any price charged on or after October 1, 1992, to the Indian Health Services, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of Section 1927 of the Social Security Act; (b) any prices charged under the Federal Supply Schedule of the General Services Administration; (c) any prices used under a State Pharmaceutical Assistance Program; and (d) any depot prices and single award contract prices, as defined by the Secretary of any agency of the Federal Government. "Best Price" shall: (a) be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section); (b) be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and (c) not take into account prices that are merely nominal in amount.

3.3 'Covered Product(s)' means the pharmaceutical product(s) [REGISTERED TRADEMARK NAME® or ™ (CHEMICAL ENTITY), DOSAGE FORM, STRENGTH].

3.4 'CMS Agreement' means the Manufacturer's drug rebate contract with the Centers for Medicare & Medicaid Services, formerly known as the Health Care Financing Administration (CMS), entered pursuant to Section 1927 of the Social Security Act (42 USC 1396r-8).

3.5 'CMS Basic Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act [42 USC l396r-8(c)(1) and 42 USC 1396r-8(c)(3)].

3.6 'CMS CPI Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act [42 USC 1396r-8(c)(2)].

3.7 'State Utilization Data' means the data used by the Department to reimburse pharmacy providers under Michigan Medicaid Program. State Utilization Data excludes data from covered entities identified in Title 42 USC 256b(a)(4) in accordance with Title 42 USC 256b(a)(4)(A) and 1396r-8(a)(5)(C).

3.8 'Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Article III, Sections 3.1 and 3.2 of this Agreement.

3.9 'Rebate Summary' means the report itemizing the State Utilization Data supporting the Department's invoice for Rebates. The Rebate Summary will comply in all respects with requirements for Medicaid Utilization Information in the CMS Agreement.

3.10 State Supplemental Rebate' means, with respect to the Covered Product(s), the quarterly payment by Manufacturer pursuant to Article III, Section 4.2 of this Agreement.

IV - MANUFACTURER'S RESPONSIBILITIES

4.1 Manufacturer will calculate and provide the Department a CMS Rebate for the Covered Product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS Rebate represents the discount obtained by multiplying the units of the Covered Product(s) reimbursed by the Department in the preceding quarter by the per unit rebate amount provided to the Department by CMS. CMS will calculate the CMS Rebate amount in accordance with Manufacturer's CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement.

4.2 In addition to the CMS Rebates described in Section 3.1 of this Agreement, each participating Manufacturer will remit to the Department a State Supplemental Rebate for the Covered Product(s). The supplemental rebate will be calculated on a calendar basis and provided via an invoice to the Manufacturer's CMS financial contact. Adjustments made for changes in volume will be completed on a quarterly basis. The State Supplemental Rebate represents the discount obtained by multiplying the excess cost per day of each Covered Product reimbursed by the Department in the preceding quarter by the quarterly aggregate days' supply for each Covered Product for the same quarter. The excess cost is determined by clinical evaluation of all products within a specific therapeutic class and comparing each clinically selected product to the best-priced clinically selected product within that category. A Manufacturer's obligation for State Supplemental Rebates will begin with the Rebate Billing Period for First calendar quarter 2002, which begins January 1, 2002, and will continue through the quarter that ends December 31, 2002.

4.3 The quarters to be used for calculating the Rebates in Sections 3.1.and 3.2 of this Agreement will be those ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.

4.4 Each participating Manufacturer will be required to submit the supplemental rebate payment within 30 days of the Manufacturer's receipt of the Rebate Summary from the Department.

4.5 Each participating Manufacturer will pay the supplemental rebate, including any applicable interest in accordance with Section 1903 (d)(5) of the Act. Interest on the Rebates payable under Section 3.1 and 3.2 of this Agreement begins accruing 38 calendar days from the postmark date of the Department's invoice and supporting Rebate Summary sent to the Manufacturer and interest will continue to accrue until the postmark date of the Manufacturer's payment. For Rebates invoiced for first calendar quarter 2002 or thereafter, if the date of mailing of the Rebate payable under Section 3.2 of this Agreement is 69 days or more from the date of mailing of the invoice, the interest rate will be calculated as required under federal guidelines, but will be increased by ten percentage points. For Rebates invoiced for first calendar quarter 2002 and thereafter, if the Department has not received the Rebates payable under Section 3.1 or 3.2 of this Agreement, including interest, within 180 days of the postmark date of the Department's invoice and supporting Rebate Summary sent to the Manufacturer, this Agreement will be deemed to be in default and will be terminated in accordance with Section 7.2 of this Agreement.

4.6 Manufacturer agrees to continue to pay supplemental rebates on the Covered Product(s) for as long as this Agreement is in force, and State Utilization Data shows that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug.

4.7 Unless notified otherwise, Manufacturer will send Rebate payments by certified mail, return receipt requested, to the following address:

Michigan Department of Community Health
Accounting – Medicaid Pharmacy Rebate
320 S. Walnut, Lewis Cass Bldg.
P. O. Box 30223
Lansing, MI 48933

V - DEPARTMENT RESPONSIBILITIES

5.1 The Department will remove prior authorization from the Manufacturer's Covered Product on the Michigan Pharmaceutical Product List. The Department will comply with all provisions of section 1927(d).

5.2 The Department will provide aggregate State Utilization Data to each participating Manufacturer on a quarterly basis. This data will be based on paid claims data (data used to reimburse pharmacy providers) for the Michigan Medicaid Program.

5.3 The Department will maintain the data systems and audits as are necessary to ensure the accuracy of the data used to calculate the supplemental rebates. In the event material discrepancies are discovered, the Department will promptly justify its data or make an appropriate adjustment, which may include a credit as to the amount of the Rebates, or a refund to Manufacturer as the parties may agree.

5.4 The Department shall maintain electronic claims records for the most recent four quarters that will permit Manufacturers to verify through an audit process the Rebate Summaries provided by the Department. The Department will also cooperate with the Manufacturer in pharmacy audit(s) should such audit(s) be required to resolve disputes regarding Utilization Information.

5.5 Upon implementation of this Agreement, and from time to time thereafter, the Department and Manufacturer will meet to discuss any data or data system improvements which are necessary or desirable to ensure that the data and any information provided by the Department to Manufacturer are adequate for the purposes of this Agreement.

VI - DISPUTE RESOLUTION

6.1 In the event that in any quarter a discrepancy in Utilization Information is noted by the Manufacturer, which the Manufacturer and the Department in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy to the Department.

6.2 If the Manufacturer in good faith believes the Department's Utilization Information is erroneous, the Manufacturer shall pay the Department that portion of the rebate claimed which is not disputed by the required date in Section 3.4. The balance in dispute, if any, will be paid or credited by the Manufacturer or the Department by the due date of the next quarterly payment after resolution of the dispute.

6.3 The Department and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of written notification. Either party may, at any time and at its own expense, hire a mutually agreed upon independent auditor to verify the accuracy of the Department's Utilization Information or the Manufacturer's calculations and payment figures. Should an audit of pharmacy records be required to resolve disputes, the Department will cooperate with the Manufacturer and provide information by zip code of pharmacy provider upon the Manufacturer's request.

6.4 In the event that the Department and the Manufacturer are not able to resolve a discrepancy within 60 days, the Manufacturer may appeal in writing to:

Department of Community Health
Administrative Tribunal & Appeals Division
Appeals Section
P.O. Box 30195
Lansing, Michigan 48909

VII – CONFIDENTIALITY PROVISIONS

7.1 Pursuant to 42 USC 1396r-8(b)(3)(D), the parties agree that confidential information will not be disclosed. Each party will treat trade secrets and other confidential information as confidential, will preserve the confidentiality and will not duplicate, disclose or use the information, except in connection with this Agreement or as may be required by judicial order.

7.2 The Manufacturer will hold the Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. The Manufacturer shall have the right to disclose Utilization Information to auditors who agree to keep such information confidential.

7.3 Notwithstanding the non-renewal or termination of this Supplemental Rebate Agreement for any reason, these confidentiality provisions will remain in full force and effect.

VIII - NON-RENEWAL or TERMINATION

8.1 Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for a defined period of time, beginning on the date certified as effective by the Department and ending per Section 9.12.

8.2 This Agreement may be terminated by either party by giving written notice to the other party at least 60 days prior to the effective date of the termination. Termination of this Agreement will result in Manufacturer's Covered Product(s) being available to the Michigan Medicaid Program beneficiaries only through prior authorization. Termination shall become effective the first day of the first calendar quarter beginning at least sixty (60) days after a party gives written notice requesting termination.

8.3 Any renewal or termination will not affect rebates due or owing on or before the effective date of termination.

IX - GENERAL PROVISIONS

9.1 This Agreement will be governed and construed in accordance with Title 42 USC Section 1396r-8; Title 42 of the Code of Federal Regulations; and all other applicable federal law and regulations.

9.2 Any notice required to be given pursuant to the terms and provisions of this Agreement will be in writing and will be sent by certified mail, return receipt requested. Notice to the Department will be sent to:

Michigan Department of Community Health
Budgets and Contracts Division
320 South Walnut
Lansing, MI 48913

Notice to Manufacturer will be sent to:

_____ (Name)
_____ (Title)
_____ (Company Name)
_____ (Address

9.3 The Manufacturer agrees to be bound by the laws of the State of Michigan and agrees that this Agreement shall be construed and interpreted in accordance with Michigan law.

9.4 Nothing herein shall be construed or interpreted as limiting or otherwise affecting the Department's ability to pursue its rights arising out of the terms and conditions of the Agreement in the event that a dispute between the parties is not otherwise resolved.

9.5 Manufacturer and the agents and employees of Manufacturer in the performance of this Agreement, will act in an independent capacity and not as officers, employees or agents of the State of Michigan.

9.6 In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner subject to the conditions in this Agreement.

9.7 Nothing in this Agreement will be construed so as to require the commission of any act contrary to law. If any provision of this Agreement is found to be invalid or illegal by a court of law, or inconsistent with federal requirements, this Agreement will be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision. The parties agree to negotiate replacement provisions, to afford the parties as much of the benefit of their original bargain as is possible.

9.8 The Department and Manufacturer declare that this Agreement, including attachments, contains a total integration of all rights and obligations of both parties. There are no extrinsic conditions, collateral agreements or undertakings of any kind. In regarding this Agreement as the full and final expression of their contract, it is the express intention of both parties that any and all prior or contemporaneous agreements, promises, negotiations or representations, either oral or written, relating to the subject matter and period of time governed by this Agreement which are not expressly set forth herein are to have no force, effect, or legal consequences of any kind.

9.9 This Agreement will not be altered except by an amendment in writing signed by both parties and approved by the appropriate State control agencies. No individual is authorized to alter or vary the terms or make any representation or inducement relative to it, unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the State and Manufacturer and approved by the appropriate State control agencies.

9.10 Neither party contemplates any circumstances under which indemnification of the other party would arise. Nevertheless, should such circumstances arise, Manufacturer agrees to indemnify, defend and hold harmless the State, its officers, agents and employees from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by the Manufacturer in the performance of this Agreement.

9.11 This Agreement is not assignable either in whole or in part without the written consent of the Department, which will not unreasonably be withheld except in accordance with Section 8.6.

9.12 This Agreement will be in effect from date of execution through December 31, 2002.

9.13 Inasmuch as the State Supplemental Rebate required by this Agreement is for Michigan Medicaid Program beneficiaries, it is agreed that the State Supplemental Rebate does not establish a new 'Best Price' for purposes of participating Manufacturer's CMS Agreement.

9.14 In the event that the Department determines, as a result of a therapeutic category review, that a Covered Product(s) of the Manufacturer included on the Michigan Pharmaceutical Product List should require prior authorization unless for appropriateness of therapy review using best practice standards, the parties agree that the terms of Section 8.2 shall apply.

As evidence of their Agreement to the foregoing terms and conditions, the parties have signed below.

Peter L. Trezise	_____ (Name)
Chief Operating Officer	_____ (Title)
Michigan Department of Community Health	_____ (Company)
Dated: _____	Dated: _____